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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/877,169	06/08/2001	Clemens Antoni Van Blitterswijk	04148-00012	9604

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EXAMINER

DEBERRY, REGINA M

ART UNIT	PAPER NUMBER
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1647

DATE MAILED: 02/27/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/877,169

Applicant(s)

VAN BLITTERSWIJK ET AL.

Examiner

Regina M. DeBerry

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 December 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 10 and 13-28 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 10 and 13-28 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☒ Certified copies of the priority documents have been received in Application No. 09/621178, 08/810266.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 5. 6) ☐ Other: _____

Status of Application, Amendments and/or Claims

The corrected or substitute drawings were received on 02 December 2002 (Paper No. 4). These drawings are acceptable.

The information disclosure statement filed 02 December 2002 (Paper No. 5) was received and complies with the provisions of 37 CFR §§1.97 and 1.98. It has been placed in the application file and the information referred to therein has been considered as to the merits.

The amendment filed 02 December 2002 (Paper No. 6) has been entered in full. New claims 13-28 were added. Claims 10 and 13-28 are under examination.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Withdrawn Objections And/Or Rejections

The objections to the drawings as set forth at page 2 of the previous Office Action (30 September 2002, Paper No. 3) is *withdrawn* in view of the corrected formal drawings submitted (02 December 2002, Paper No. 4).

The rejection of claim 10 under 35 USC 112, second paragraph as set forth at pages 2-3 of the previous Office Action (30 September 2002, Paper No. 3) is *withdrawn* in view of the amendment (02 December 2002, Paper No. 6).

The rejection of claim 10 under 35 USC 102(b) as being anticipated by Cantor *et al.*, US Patent No. 4,722,998 as set forth at pages 4-5 of the previous Office Action (30 September 2002, Paper No. 3) is *withdrawn* in view of the amendment

(02 December 2002, Paper No. 6).

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 10, 13-19 are rejected under 35 U.S.C. § 112, first paragraph, as the specification does not contain a written description of the claimed invention, in that the disclosure does not reasonably convey to one skilled in the relevant art that the inventor(s) had possession of the claimed invention at the time the application was filed. This is a new matter rejection. The specification as originally filed does not provide support for the invention as now claimed: "A method of producing active factors comprising the steps of: (b) contacting the cells with a culture medium for a sufficient time to produce a matrix".

Applicant's amendment, filed 02 December 2002 (Paper No. 6), asserts that no new matter has been added. Directs support to page 2, lines 3-4 for the written description for the above-mentioned "limitations", however this step is in a method for in vitro production of bone tissue, not a method for producing active factors.

The specification as filed does not provide a written description or set forth the metes and bounds of this "limitations". The specification does not provide blazemarks nor direction for the instant methods encompassing the above-mentioned "limitations" as they are currently recited. The instant claims now recite limitations which were not

clearly disclosed in the specification as filed, and now change the scope of the instant disclosure as-filed. Such limitations recited in the present claims, which did not appear in the specification, as filed, introduce new concepts and violate the description requirement of the first paragraph of 35 U.S.C. 112.

Applicant is required to cancel the new matter in the response to this Office action. Alternatively, Applicant is invited to provide specific written support for the "limitations" indicated above or rely upon the limitations set forth in the specification as filed.

Claim Rejections - 35 USC § 102

Claims 20-28 are rejected under 35 U.S.C. 102(b) as being anticipated by Gronthos *et al.* (Blood, Vol. 84, No.12, 4164-4173, 1994, IDS, Paper No. 5).

The claims are generally drawn to a method of producing bone growth factors comprising the steps of: applying bone marrow cells or stromal cells on a substrate, contacting the bone marrow or stromal cells with a culture for a sufficient time produce bone growth factors and recovering the bone growth factors from the substrate.

Gronthos teaches the culturing of bone marrow stromal cell progenitors (fibroblast colony-forming units, CFU-F) from adult human bone marrow (autologous)(abstract and page 4165, materials and methods). These cells were capable of forming a layer *in vitro* consisting of stromal cell types (page 4165, 2nd paragraph). After two weeks of culture, all of the CFU-colonies grown in the presence of ASC-2P, DEX and PO4 were found to express alkaline phosphatase, which is a well-

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documented marker of bone cell differentiation (page 4167, 2nd paragraph). The adherent layers of bone marrow cultures after 4 weeks in osteogenic conditions displayed large areas of mineralized material (page 4167, 3rd paragraph). Six-week-old mineralized bone marrow cultures were washed in PBS and serum starved. The biosynthesis of osteocalcin (osteoblast-specific protein factor and indicator of bone formation) was stimulated by the addition of 1,25-Vit D3. Samples were taken from the medium of the cultures and analyzed for the presence of osteocalcin.

Conclusion

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

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extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Regina M. DeBerry whose telephone number is (703) 305-6915. The examiner can normally be reached on Mondays-Fridays 8:00 a.m. - 4:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached on (703) 308-4623. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.



RMD
February 21, 2003



GARY KUNZ
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600